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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/519,148	03/06/00	LIPSHUTZ	R 18547-009911

020350 HM12/0803  
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EXAMINER

SISSON, B

ART UNIT PAPER NUMBER

1655

*2*

DATE MAILED:

08/03/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Application No. 09/519,148	Applicant(s) LIPSHUTZ ET AL.
Examiner Bradley L. Sisson	Art Unit 1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

- 1)  Responsive to communication(s) filed on 06 March 2000.
- 2a)  This action is FINAL.
- 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 80-107 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 80-107 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.
- 12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
a)  All b)  Some \* c)  None of the CERTIFIED copies of the priority documents have been:  
1.  received.  
2.  received in Application No. (Series Code / Serial Number) \_\_\_\_\_ .  
3.  received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- 15)  Notice of References Cited (PTO-892)
- 16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_ .
- 19)  Notice of Informal Patent Application (PTO-152)
- 20)  Other: \_\_\_\_\_ .

## **DETAILED ACTION**

### *Location of Application*

1. The location of the subject application has changed. The subject application is now located in Group 1650, Art Unit 1655, and has been assigned to Primary Examiner Bradley L. Sisson.

### *Drawings*

2. The drawings are objected to for reasons as stated on FORM PTO-948 (Rev. 8-98). Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

### *Sequence Rules*

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

*Specification*

1. The disclosure is objected to because of the following informalities:

The specification needs to be amended such that the current status of cited application is correctly indicated.

Appropriate correction is required.

*Claim Rejections - 35 USC § 102/103*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102((e), f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 80-83, 85-96, and 98-107 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wilding et al.

Wilding et al., at columns 20-24 disclose a method for extracting and purifying DNA and subsequently performing an amplification reaction of same followed by detection of the amplification product. As can be seen in said columns, the reactions are performed in an apparatus that is comprised of at least two reaction chambers and that the sample is caused to move from one reaction chamber to another.

Column 18 discloses the adaptation of devices so to effect fluid movement and the separation of nucleic acid sequences via electrophoresis. In view of the miniscule size of the apparatus disclosed, such is considered to meet the limitation of "microcapillary electrophoresis" (claims 83 and 96).

The aspect of isolating nucleic acid from a sample is considered to meet the limitation of "neutralizing and infectious agent or performing pH adjustment."

6. Claims 84 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al., (US Patent 5,587,128) as applied to claim 80-83, 85-96, and 98-107 above, and further in view of Schnipelsky et al., and Fodor et al. (US Patent 5,424,186).

Wilding et al., at columns 20-24 disclose a method for extracting and purifying DNA and subsequently performing an amplification reaction of same followed by detection of the amplification product. As can be seen in said columns, the reactions are performed in an

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apparatus that is comprised of at least two reaction chambers and that the sample is caused to move from one reaction chamber to another.

Column 18 discloses the adaptation of devices so to effect fluid movement and the separation of nucleic acid sequences via electrophoresis. In view of the miniscule size of the apparatus disclosed, such is considered to meet the limitation of "microcapillary electrophoresis" (claims 83 and 96).

The aspect of isolating nucleic acid from a sample is considered to meet the limitation of "neutralizing and infectious agent or performing pH adjustment."

Wilding et al., do not disclose the aspect of an array of probes for conducting a hybridization reaction with an amplification product.

Schnipelsky et al., disclose a capillary device used in conducting amplification reactions. As seen in Fig. 1 and Fig. 3, there is found a region of the device wherein is located an array of probes (see also column 13, second paragraph).

The size of the channels disclosed by Schnipelsky et al., are not considered to constitute a "microcapillary."

Fodor et al., disclose a method whereby arrays of nucleic acid sequences are synthesized onto minute areas of a solid support.

It would have been obvious to one of ordinary skill in the art to have modified the apparatus of Wilding et al., with the teachings of Schnipelsky et al., and Fodor et al., so to arrive at a method of preparing a nucleic acid sample, amplifying and detecting an amplification product whereby all of said steps are performed in a microfluidic device. In view of the well developed aspect of the prior art, and the explicit teachings of combining a variety of

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steps/procedures into a single device, the ordinary artisan would have been highly motivated to have devised such an apparatus and method and would have had a reasonable expectation of success.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*B. L. Sisson*  
Bradley L. Sisson  
Primary Examiner  
Art Unit 1655

BLS  
July 29, 2000